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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,298	04/07/2004	John Sefton	17224CON (AP)	7456
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ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599				
EXAMINER				
BADJO, BARBARA P				
ART UNIT		PAPER NUMBER		
1628				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,298

Applicant(s)

SEFTON, JOHN

Examiner

Barbara P. Badio

Art Unit

1628

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.6 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1.6 and 11-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

Nonfinal Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1, 6 and 11-13 are pending in the present application. The instant claims stand rejected as indicated below.

Specification

3. **Applicant argues all trademarks are capitalized with generic terminology provided.**

The examiner notes that according to MPEP § 608.01(v) (I):

if the product to which the trademark refers is set forth in such language that its identity is clear, the examiners are authorized to permit the use of the trademark if it is distinguished from common descriptive nouns by capitalization.

In the previous Office Action, the examiner identified several trademarks found in the present specification that are not capitalized as required by the MPEP. Correction is required.

Double Patenting

4. The rejection of claims 4, 5, 10 and 14 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,974,807 is made moot by the cancellation of the instant claims.

5. The rejection of claims 1, 6 and 11-13 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,974,807 is maintained.

The terminal disclaimer filed January 19, 2010 does not comply with 37 CFR 1.321(b) and/or (c) because: An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Claim Objections

6. The objection to claims 4 and 5 under 37 CFR 1.75(c), as being of improper dependent is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 112

7. The rejection of claims 4, 5, 10 and 14 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is made moot by the cancellation of the instant claims.

8. The rejection of claims 1, 6 and 11-13 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

Claim Rejections - 35 USC § 103

9. The rejection of claims 1, 6, 12 and 13 under 35 USC 103(a) over Yamamoto (US 5,236,906) and Nagpal et al. (US 5,650,279) is withdrawn.

10. Claims 1, 6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto (US 5,236,906) or Shimizu et al. (US 6,248,779) and Nagpal et al. (US 5,650,279).

Each of Yamamoto and Shimizu et al. teaches the use of adrenocortical hormones, such as betamethasone valerate and/or alclometasone dipropionate, in the treatment of dermatoses such as atopic dermatitis and/or psoriasis (see '906, col. 1, line 11 – col. 2, line 55; '779, col. 1, lines 10-18; col. 2, lines 20-29; col. 6, lines 40-65).

Nagpal et al. teaches it is known in the art to use tazarotene in the treatment of psoriasis and exemplifies the use of a 0.05% cream (see col. 1, lines 42-47; Example 9).

The instant claims differ from the cited references by reciting the treatment of proliferative skin diseases by the administration of an effective amount of about 0.1% to about 2% tazarotene gel and an effective amount of a corticosteroid, i.e., alclometasone dipropionate and/or betamethasone valerate.

As recognized by MPEP § 2144.06(I):

“It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be

used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious). **

Thus, the combination of the compounds taught by Yamamoto/Shimizu and Nagpal for the treatment of dermatoses to a patient in need of said treatment would have been *prima facie* obvious to the skilled artisan in the art at the time of the present invention. As noted above, the idea to combine flows logically from their having been individually taught in the prior art for treatment of dermatoses, including psoriasis and atopic dermatitis, i.e., the same disorder(s).

Claim 11 further differ from the cited references by reciting the administration of tazarotene once daily in the evening and the corticosteroid once daily in the morning. However, the medical art teaches combination therapy as well as administration of the drugs involve in combination therapy at different times during the day. In addition, absence a showing of criticality of the order and/or time of administration of the drugs in a combination therapy, said recitation is not considered a patentable limitation.

11. The rejection of claims 1, 6, 12 and 13 under 35 USC 103(a) over Smith (US 5,874,074) or Sequeira et al. (US 4,775,529) and Nagpal et al. (US 5,650,279) is maintained and claim 11 is rejected under 35 USC 103(a) over Smith (US 5,874,074) or Sequeira et al. (US 4,775,529) and Nagpal et al. (US 5,650,279).

The rejection is maintained for the reasons given in the previous Office Action. Additionally, it is noted that Smith also teaches "alclometasone dipropionate" (see col. 4, line 64). Thus, as noted in the previous Office Action and above in #10, the combination therapy of the claimed invention is prima facie based on teachings by the cited prior art of similar use(s) of tazarotene and corticosteroids.

Also as noted above in #10, the recitation of order and/or time of administration of the drugs in the claimed combination therapy do not lend patentability to an obvious treatment method absence a showing of criticality of said limitation. Therefore, claim 11 is rendered obvious.

Other Matters

12. Applicant's attention is directed to the decision of the Board of Patent Appeals and Interferences dated September 24, 2003 in regards to mid-potency corticosteroid, i.e., alclometasone dipropionate.

Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1628